K123085

6.0

510(k) Summary

DEC 2 0 2012

Date Prepared:	September 7, 2012
Name and Address of Manufacturer:	3M Company 2510 Conway Avenue St. Paul, MN 55144
Contact Person:	Lisa Nelson Regulatory Affairs (651)733-2334 lfnelson1@mmm.com
Trade Name:	FUTURO™ Travel Knee-Highs FUTURO™ Travel Socks FUTURO™ Travel Stocking FUTURO™ Travel Pantyhose
Common Name:	Stocking, medical support (to prevent pooling of blood in legs)
Regulation Number:	21 CFR 880.5780
Classification Name:	Medical support stocking
Regulatory Class:	II
Classification Panel:	General Hospital
Product Code:	DWL

Predicate Devices:
K032325 Travel Sock – BSN-Jobst, Inc.
K101906 Shape to Fit Compression Socks – Tsung Hau Technology Company, Limited

Indications for use:

Help prevent edema and leg discomfort and help prevent deep vein thrombosis in individuals subjected to immobility or long distance travel.

Over the counter use.

Device Description:
The FUTURO™ Travel Knee-Highs, Socks, Stockings and Pantyhose are made of a blend of nylon and spandex. The FUTURO™ Travel Knee-Highs, Socks, Stockings and Pantyhose provide graduated compression of the leg, with the higher compression in the ankle region and lower compression in the calf and the thigh (for the pantyhose only). Two compression ranges are available, Moderate, 15-20 mmHg, and Firm, 20-30mmHg. The compression hosiery products are produced on circular knitting machines. Performance testing of the products demonstrates that the compression hosiery meet the stated compression specification ranges and provide the same compression levels as the predicate devices.

The FUTURO™ Travel Knee-Highs, Socks, Stockings and Pantyhose are substantially equivalent to the predicate products in product materials, mode of action, compression levels, function and indication for use, and as such, can be considered safe and effective as the referenced, predicate products. Like the predicate products, the FUTURO™ Travel Knee-Highs, Socks, Stockings and Pantyhose are available in a variety of colors and sizes for both men and women.

The FUTURO™ Travel Knee-Highs, Socks, Stockings and Pantyhose differ from the predicate devices in the following aspects. Tsung Hau Technology Company, Limited, Shape to Fit, compression hosiery utilizes a "fresh weave odor control". The 3M FUTURO™ hosiery does not. Jobst's Travel Sock contains cotton yarn for comfort. The 3M FUTURO™ hosiery does not contain any cotton (with the exception of the cotton lined crotch in the pantyhose). No other significant differences are noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2012

Ms. Lisa Nelson
Regulatory Affairs Specialist
3M Company
3M Consumer Health Care Division
2510 Conway Avenue
St. Paul Minnesota 55144

Re: K123085
Trade/Device Name: FUTURO™ Travel Knee-Highs, FUTURO™ Travel Socks, FUTURO™ Travel Stocking, FUTURO™ Travel Pantyhose
Regulation Number: 21 CFR 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: October 1, 2012
Received: October 16, 2012

Dear Ms. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 Indications for Use Statement

510(k) Number: K123085

Device Name: FUTURO™ Travel Knee-Highs, Socks, Stockings and Pantyhose

Indications for Use:

Help prevent edema and leg discomfort and help prevent deep vein thrombosis in individuals subjected to immobility or long distance travel.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Richard C. Chapman
Date: 2012.12.18 14:00:38 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123085